REMARKS

Applicant respectfully requests entry of the amendments and remarks submitted herein. Claims 1, 18, 19, 21, 23-25, 31, 32, and 34 have been amended and new claim 35 has been added. The claim amendments serve to clarify the claim language. Support for new claim 35 can be found, for example, on page 13, lines 8-21, and in Figures 27-29. Claims 1-35 are currently pending. Attached is a marked-up version of the changes being made by the current claim amendments.

Figures 3 and 42 also were amended herein. A copy of the amended figures showing the amendments in red ink is provided.

Reconsideration of the pending application is respectfully requested.

The Drawings

The Examiner indicated that the drawings stand objected to for failing to comply with 37 CFR 1.84(p)(5) because they do not include the reference sign "longitudinal channel 133" mentioned in the description. The Examiner is requiring a proposed drawing correction or corrected drawings.

Applicants herewith include formal drawings corresponding to Figures 1-42. Figure 3 has been amended to show a "longitudinal channel 133." Figure 42 also has been amended to include identifying numbers discussed in the text but not shown in the figure. These amendments clarify the drawings and do not introduce new matter. In view of the enclosed formal drawings, Applicants respectfully request that the objection to the drawings be withdrawn.

The 35 U.S.C. §112 Rejections

Claims 19, 20 and 24 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner stated that there is insufficient antecedent basis for the use of "the second channel" in claim 19 and "the opening in the intramedullary rod" in claim 24. Applicants have herein amended claims 19 and 24.

In view of the claim amendments herein, Applicant respectfully request that the rejection of claims 19, 20, and 24 under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 1-3, 7-8, 14, 17, 21-24 and 30-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Border (U.S. Patent No. 5,935,127). Claims 1-3, 7-8, 14-24 and 30-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Moehring (U.S. Patent No. 4,846,162). Claims 1-3, 7-8, 14-15, 17-24 and 30-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Durham et al. (U.S. Patent No. 6,106,528; hereafter 'Durham'). Claims 1, 4-8 and 11-13 stand rejected under 35 U.S.C. §102(e) as being anticipated by Cole et al. (U.S. Patent No. 6,221,074; hereafter 'Cole'). These rejections are respectfully traversed.

Claim 1 has been amended herein to recite "at least one tine." None of the cited references teach using a tine to secure an intramedullary rod to a bone. In addition, none of the cited references teach an intramedullary rod configured to receive one of the claimed tines. For example, claims 17-20 recite that the tine is mounted to the intramedullary rod (*e.g.*, threadably mounted in claims 18-20); claims 21-24 recite that the tine includes an insert; claim 25 recites a snap-fit tine; and claim 35 recites a press-fit tine. Applicant respectfully refers the Examiner to Figures 11-29 of the instant application (and the accompanying Figure description), and pages 10, line 20 through page 13, line 21, which show and describe the tines and their attachment to the intramedullary rod.

With respect to Durham, the Examiner indicated that the screws shown in Figures 39 and 41 of Durham are considered to be tines. As discussed in the paragraph above, the tines and the manner in which the intramedullary rod receives such tines are very different than the screws and the intramedullary nail shown in Figures 39 and 41 of Durham.

None of the cited references (Border, Moehring, Durham, nor Cole) teach each and every element of the claimed invention. Particularly, none of the cited references teach a tine, as amended claim 1 recites. Therefore, Applicant respectfully requests that the rejection of claims

1-3, 7-8, 14, 17, 21-24 and 30-32 under 35 U.S.C. §102(b) over Border; of claims 1-3, 7-8, 14-24 and 30-32 under 35 U.S.C. §102(b) over Moehring; of claims 1-3, 7-8, 14-15, 17-24 and 30-32 under 35 U.S.C. §102(b) over Durham; and of claims 1, 4-8 and 11-13 under 35 U.S.C. §102(e) over Cole be withdrawn.

The 35 U.S.C. §103 Rejections

Claims 4-6 and 9-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Border in view of Matthews (U.S. Patent No. 5,779,705). This rejection is respectfully traversed.

Claim 1 has been amended to recite that the claimed intramedullary rod kit includes at least one tine. Border does not teach or suggest using a tine.

According to the Examiner, Matthews discloses an intramedullary nail that can be manufactured in varying lengths and diameters from a biologically inert material that is sterilized and has appropriate mechanical strength. The Examiner asserted that it would have been obvious to one of ordinary skill at the time of the invention to incorporate the variable lengths and diameters as taught by Matthews into the kit disclosed by Border in order to provide the appropriate dimensions for easier, more secure insertion in the bone.

Border does not teach or suggest each and every element of the claimed invention. Even if Matthews teaches lengths and diameters of an intramedullary nail that are appropriate for fixation of a distal radius fracture, neither Border or Matthews teaches or suggests a tine or the claimed configurations for attaching a tine to an intramedullary rod.

Matthews, Border, or Matthews and Border in combination, do not make obvious the claimed intramedullary rod kit that includes an intramedullary rod and a tine. Accordingly, Applicant respectfully request that the rejection of claims 4-6 and 9-10 under 35 U.S.C. §103(a) be withdrawn.

Claims 28-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Border in view of Allen et al. (U.S. Patent No. 5,979,658; hereafter 'Allen'). This rejection is respectfully traversed.

Claim 1 has been amended to recite that the claimed intramedullary rod kit includes at least one tine. Border does not teach or suggest using a tine.

According to the Examiner, the kit disclosed by Allen provides an instructional video and written instructions. The Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include written instructions and an instructional video into a kit since it was known in the surgical art that physicians and/or patients might require training on the use of products.

Border does not teach or suggest each and every element of the claimed invention. Even if Allen discloses the use of written instructions and/or an instructional video, neither Border or Allen teaches or suggests a tine or the claimed configurations for attaching a tine to an intramedullary rod.

Allen, Border, or Allen and Border in combination, do not make obvious the claimed intramedullary rod kit that includes both an intramedullary rod and a tine. Accordingly, Applicant respectfully request that the rejection of claims 28-29 under 35 U.S.C. §103(a) be withdrawn.

Claims 33-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Border in view of Cachia et al. (U.S. Publication No. 2001/0049529; hereafter 'Cachia'). Applicants respectfully traverse this rejection.

Claim 1 has been amended to recite that the claimed intramedullary rod kit includes at least one tine. Border does not teach or suggest using a tine. With respect to this rejection, the Examiner admitted that Border does not disclose a kit in which the diaphyseal surface of the rod comprises dimples and where there is a therapeutic coating on the rod or the tine.

According to the Examiner, Cachia discloses a bone fixation device with an elongated body where a "micropitted or otherwise textured surface" is provided "on the anchor components," and further discloses that "the anchor components of the invention may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like." The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the

invention to incorporate a textured surface and bioactive coating as taught by Cachia to the intramedullary rod disclosed by Border in order to enhance osteoincorporation and to contribute to the healing of the injury in addition to providing mechanical support, respectively.

Border does not teach or suggest each and every element of the claimed invention. Even if Cachia discloses the use of a textured surface and/or a bioactive coating, neither Border or Cachia teaches or suggests a tine or the claimed configurations for attaching a tine to an intramedullary rod.

Cachia, Border, or Cachia and Border in combination, do not make obvious the claimed intramedullary rod kit having both an intramedullary rod and a tine. Accordingly, Applicant respectfully request that the rejection of claims 33-34 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant acknowledges the Examiner's indication of allowable subject matter in claims 25-27. In view of the amendments and remarks herein, Applicant asks that claims 1-35 be allowed. Enclosed is a check in the amount of $214 ($205 for the Two-Month Petition for Extension of Time fee and $9 for the excess claim fee). Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The Figure legend on page 4, line 14 was amended as follows:

Fig. 11 is a side view of an intramedullary rod configured to receive individual [times] tines.

The Figure legend on page 5, line 9 was amended as follows:

Fig. 32 is a side view of a fastener for use with [a] the tie band of Fig. [3130] 30.

The paragraph on page 9, lines 14-20 was amended as follows:

Although Fig. 10 shows five drill guides 325 positioned within the aiming piece 315, the guide 300 may be accompanied by a single drill guide 325 that can be removed and reinserted in another channel 320. Fig. 10 also shows the proximal-most channel 115 being positioned at a [of] 90° rotation from the other mounting sections or channels 115, 120. The guide 300 is configured such that the handle 310 can be moved relative to the mounting piece 305 in 90° increments so that the channels 320, drill guides 325, and the channels 115 and 120 are aligned.

The paragraph on page 11, lines 16-22 was amended as follows:

Referring to Fig. 16, the tines 405 can be spaced apart such that a bone screw or tensioning device can be passed through the intramedullary rod 400 from a different orientation than the tines to further secure the rod to the bone fragments. This provides additional fixation of the rod to the bone fragments. By securing [be] the rod to the bone fragments from a different orientation, undesirable rotation and movement of the bone fragments is further restricted. Of course, the bone screw or tensioning device can be configured as the threaded tine 425.

In the Claims:

New claim 35 has been added herein. Claims 1, 18, 19, 21, 23-25, 31, 32 and 34 have been amended as follows:

1. (Amended) An intramedullary rod kit for fixation of a distal radius fracture, the intramedullary rod kit comprising:

an intramedullary rod comprising:

a diaphyseal segment including at least one first mounting section configured to receive a tensioning device,

a middle segment; and

a joint segment including at least one second mounting section configured to receive a tine,

wherein the diaphyseal segment, the middle segment, and the joint segment define a curved configuration that is substantially similar to a curvature of the intramedullary canal of a human radius; and

at least one tine.

18. (Amended) The intramedullary rod kit of claim 17 wherein the second mounting section comprises a channel that includes a threaded portion and wherein the tine includes a first non-threaded section and a second threaded section, wherein the second threaded section [that] is configured to be threadably mated to the threaded portion of the channel.

19. (Amended) The intramedullary rod kit of claim 17 wherein the second mounting section comprises a channel that includes a threaded portion and wherein the tine includes a first threaded section and a second threaded section, wherein the second threaded section [that] is configured to be threadably mated to the threaded portion of the channel.

21. (Amended) The intramedullary rod kit of claim 1 wherein the tine comprises an insert from which at least one shaft extends and wherein the insert is configured to be mated to the second mounting section.

23. (Amended) The intramedullary rod kit of claim 22 wherein the insert includes a channel configured to receive a screw and wherein the intramedullary rod includes a threaded channel configured to receive the screw.

24. (Amended) The intramedullary rod kit of claim 23 wherein the threaded channel [opening in the intramedullary rod] further comprises an opening extending through the intramedullary rod and configured to receive the shaft.

25. (Amended) The intramedullary rod kit of claim 1 [further comprising] wherein the tine is a snap fit tine including a head having an opening into which teeth protrude and from which a [tine] shaft extends and wherein the second mounting section includes a channel around at least a portion of the circumference of the intramedullary rod and from which teeth protrude and wherein the head is configured to be mated with the second mounting section.

31. (Amended) The intramedullary rod kit of claim 1 further comprising a tensioning device, wherein the tensioning device comprises a tie band fastener including a tie band, a slidable tab, and a stop.

32. (Amended) The intramedullary rod kit of claim 1 further comprising a tensioning device, wherein the tensioning device comprises a molly bolt system that includes a head, a nut, and one or more flexible arms extending between the head and the nut.

34. (Amended) The intramedullary rod kit of claim 1 wherein the intramedullary rod, [the tensioning device,] and/or the tine are coated with a therapeutic agent.

35. (New) The intramedullary rod kit of claim 1 wherein the tine comprises a press-fit tine including a head from which a shaft extends, wherein the shaft includes a stop, wherein the head and stop are configured to be mated with the second mounting section.

In the Drawings:

Figure 3 has been amended to include a "longitudinal channel 133" discussed in the specification.

Figure 42 has been amended to include the reference numerals disclosed in the specification.

The informal drawings presently in the application have been replaced with the attached formal drawings.